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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte THORSTEN FEIWEIER, DIANA MARTIN, GUNTHER PLATSCH, SEBASTIAN SCHMIDT, KRISTIN SCHMIEDEHAUSEN, and MICHAEL SZIMTENINGS[1]

Appeal 2015-001432
Application 12/219,609
Technology Center 3700

Before DONALD E. ADAMS, JEFFREY N. FREDMAN, and TIMOTHY G. MAJORS, *Administrative Patent Judges*.

PER CURIAM

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 involving claims to a method and an image arrangement for detecting a brain region with neurodegenerative change which have been rejected as indefinite and obvious. We have jurisdiction under 35 U.S.C. § 6(b).

We affirm-in-part.

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[1] Appellants identify the Real Party in Interest as Siemens Aktiengesellschaft. (App. Br. 4.)

STATEMENT OF THE CASE

Appellants' invention "generally relate[s] to a computerized method for detecting a brain region with neurodegenerative change and also a brain region with vascular change in the brain of a patient, a corresponding computer program, a data storage medium on which the computer program is saved, and/or an imaging arrangement for carrying out the method." (Spec. ¶ 2.) More specifically, Appellants disclose that an "MRI image is subdivided by segmentation into gray matter and white matter - for example into cortex and non-cortex - and the result of the segmentation is transferred to the PET image by fusion with it." (*Id.* at ¶ 10; *see also id.* at ¶ 39.)

Claims 1–8 and 10–21 are on appeal. Claim 1 is illustrative:

> 1. A computerized method for detecting a brain region with neurodegenerative change and also a brain-region with vascular change in the brain of a patient, the computerized method comprising:
>
> recording a positron emission data record of the brain via positron emission tomography and a magnetic resonance data record of the brain via magnetic resonance imaging, the recording of the positron emission data record and the magnetic resonance data record being carried out one of in succession without repositioning the patient, or simultaneously;
>
> reconstructing a PET image from the positron emission data record and an MRI image from the magnetic resonance data record;
>
> identifying evidence for a brain region with vascular change in the MRI image;
>
> segmenting the MRI image into gray matter and white matter;
>
> identifying a brain region with neurodegenerative change in the PET image; and

> superposing, in response to observing a changed brain region in the PET image, the PET image and the segmented MRI image to determine whether the identified brain region with neurodegenerative change is present in gray matter or in white matter.

(App. Br. 43 (Claims App'x).)

The claims stand rejected as follows:

I. Claim 21 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite.

II. Claims 1, 4–6, 10, 11, 18, and 19 are rejected under 35 U.S.C. § 103(a) over Schlyer,[2] Mark,[3] and Sibbitt.[4]

III. Claims 2 and 13–15 are rejected under 35 U.S.C. § 103(a) over Schlyer, Mark, Sibbitt, and Mueller.[5]

IV. Claim 3 is rejected under 35 U.S.C. § 103(a) over Schlyer, Mark, Sibbitt, and Weese.[6]

V. Claims 7 and 8 are rejected under 35 U.S.C. § 103(a) over Schlyer, Mark, Sibbitt, and Salb.[7]

VI. Claim 12 is rejected under 35 U.S.C. § 103(a) over Schlyer, Mark, Sibbitt, Mueller, and Weese.

VII. Claims 16 and 17 are rejected under 35 U.S.C. § 103(a) over Schlyer, Mark, Sibbitt, Mueller, and Salb.

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[2] Schlyer et al., US 2005/0113667 A1, published May 26, 2005.
[3] Mark et al., *Amyloid β-Peptide Impairs Glucose Transport in Hippocampal and Cortical Neurons: Involvement of Membrane Lipid Peroxidation*, 17 THE JOURNAL OF NEUROSCIENCE 3:1046–1054 (1997).
[4] Sibbitt et al., US 6,385,479 B1, issued May 7, 2002.
[5] Mueller, US 5,732,702, issued Mar. 31, 1998.
[6] Weese et al., US 2005/0226527 A1, published Oct. 13, 2005.
[7] Salb, US 6,226,352 B1, issued May 1, 2001.

VIII. Claim 20 is rejected under 35 U.S.C. § 103(a) over Schlyer, Mark, Sibbitt, and Marks.[8]

IX. Claim 21 is rejected under 35 U.S.C. § 103(a) over Schlyer, Mark, Sibbitt, Mueller, and Marks.

REJECTION I

The Examiner determines that "[i]t is not clear whether the functional magnetic resonance data record recited in [] claim [21] is the same record as the magnetic resonance data record recited in claim 1." (Ans. 7.)

We are not persuaded. As Appellants explain, "[t]he recitation of 'functional magnetic resonance data record' in claim 21 refers back to the initial recitation of this feature in claim 2, and is not the same record as the 'magnetic resonance data record,' recited in claim 1." (Reply Br. 2.)

We thus reverse the rejection of claim 21 as being indefinite.

REJECTION II

Claims 1, 4–6, 10, and 19:

The Examiner finds that

> Schlyer discloses a device and method comprising means for recording a positron emission data record of the brain via positron emission tomography (PET imager, abstract) and means for recording a magnetic resonance data record of the brain via magnetic resonance imaging (MRI imager, abstract), means for reconstructing a PET image from the first data record and an MRI image from the second data record (abstract)[,] means for identifying evidence for a brain region with vascular change in the MRI image, means for identifying a brain region with glucose

[8] Marks, US 2006/0084858 A1, published Apr. 20, 2006.

> uptake changes in the PET image and means for superposing the PET image and an MRI image to determine whether an identified brain region with neurodegenerative change is present[,] the recording of the first data record and the second data record being carried out one of in succession without repositioning the patient, or simultaneously ([0008], [0016], [0040], [0041], [0057]).

(Ans. 8–9.)

The Examiner concludes that

> [a]lthough Schlyer does not disclose superposing the PET image with the segmented MRI image in response to observing a changed brain region in the PET image, it would have been obvious to one having ordinary skill in the art at the time of invention to do so since Schyler discloses in paragraph 0016 that the combination of PET and MRI image is useful since it allows one to get a fuller understanding of the actual state of the patient by linking the structural aspects and functional aspects of the region of interest stating "There are many reasons for combining the functional information from PET with the anatomical (MRI), functional (fMRI) and spectroscopic (MRS) images that can be obtained with MR systems. For example,. . . accurate registration of PET and MR images . . .".

(*Id.* at 9.)

The Examiner finds that "Schlyer fails to disclose segmenting MRI images into gray matter and white matter to determine whether changes have occurred in grey or white matter." (*Id.* at 10.)

The Examiner turns to Mark and Sibbitt, and finds that "Mark discloses that changes in glucose uptake in the brain [is] indicative of neurodegenerative changes (pg. 1046). Sibbitt discloses segmenting the MRI image into gray matter and white matter for the purpose of diagnosing brain disease (col. 5[,] lines 24–41)." (*Id.*) The Examiner concludes that it would have been obvious to

> modify Schlyer's method and apparatus, for determining neurodegenerative changes in the brain using PET since Schlyer discloses using PET for determining changes in the uptake of glucose in the brain and Mark discloses changes in glucose uptake in the brain being indicative of neurodegenerative changes. It would also have been obvious . . . to modify Schlyer's method and apparatus by providing means for segmenting the MRI images, as disclosed by Sibbitt, in order to improve the diagnostic capacity of the device and method in diagnosing brain disease.

(*Id.* at 10.)

The issue with respect to this rejection is: Does the evidence of record support the Examiner's conclusion that Schlyer, as evidenced by Mark, and Sibbitt, render claim 1 obvious?

Findings of Fact

1. Schlyer teaches

> A combined PET/MRI scanner generally includes a magnet for producing a magnetic field suitable for magnetic resonance imaging, a radiofrequency (RF) coil disposed within the magnetic field produced by the magnet and a ring tomograph disposed within the magnetic field produced by the magnet. The ring tomograph includes a scintillator layer for outputting at least one photon in response to an annihilation event, a detection array coupled to the scintillator layer for detecting the at least one photon outputted by the scintillator layer and for outputting a detection signal in response to the detected photon and a front-end electronic array coupled to the detection array for receiving the detection signal, wherein the front-end array has a preamplifier and a shaper network for conditioning the detection signal.

(Schlyer Abstract; *see also* Ans. 8.)

2. Schlyer teaches that

> although PET provides advanced functional information with a very high sensitivity, a major problem in PET imaging is the lack

> of anatomical information. . . . While CT provides excellent contrast for bone structures, magnetic resonance imaging (MRI) yields excellent soft tissue contrast. Therefore, it would be desirable to combine the diagnostic benefits of a PET scanner with those of an MRI scanner.

(Schlyer ¶ 15; *see also* Ans. 16–17.)

3. Schlyer teaches

> There are many reasons for combining the functional information from PET with the anatomical (MRI), functional (fMRI) and spectroscopic (MRS) images that can be obtained with MR systems. For example, exploring relationships between structure and function by simultaneous mapping of PET and MR images, the ability to compare different brain mapping techniques such as fMRI and PET, accurate registration of PET and MR images, partial volume correction of PET data, temporal correlation of PET and MR spectroscopic images and motion correction of PET studies to permit imaging in conscious animals.

(Schlyer ¶ 16; *see also* Ans. 8–9 and 15–18.)

4. Mark teaches that "[a] deficit in glucose uptake and a deposition of amyloid β-peptide (Aβ) each occur in vulnerable brain regions in Alzheimer's disease (AD)." (Mark Abstract, *see also* Ans. 9.)

5. Sibbitt teaches

> The diagnostic ability of MRI in brain diseases has been improved by the application of image processing (segmentation of gray and white matter) to provide quantitative measures of T_2 which have special value in the diagnosis of disease. The present invention includes the following novel features: 1) segmentation of gray matter and tissues using a number of different techniques, 2) exclusion of partial volume artifacts, 3) calculation of T_2 on a pixel by pixel basis using conventional mathematical formulae, 4) use of the T_2 values—primarily of gray matter—to diagnose specific diseases, and 5) pixel histogram analysis to determine the pattern of involvement. Powerful data is provided below that confirms both the uniqueness and the particular value of these

> specific measures to diagnose brain disease and brain disease activity. This invention has wide applicability to the diagnosis of disease, particularly inflammatory, metabolic, and post-traumatic brain disease.

(Sibbitt 5:25–41; *see also* Ans. 9.)

DISCUSSION

We are not persuaded that the Examiner has established by a preponderance of the evidence that claim 1 would have been obvious.

Claim 1 is drawn to a "*method* for detecting a brain region with neurodegenerative change and also a brain-region with vascular change in the brain of a patient" — as opposed to "an imaging arrangement." (*See* App. Br. 43 (Claims App'x); *compare e.g.,* claims 11 and 18 (App. Br. 45 and 47 (Claims App'x).) The Examiner has not sufficiently explained where Schlyer, Mark, or Sibbitt teach or suggest the claimed limitation of "identifying evidence for a brain region with vascular change in the MRI image."

The Examiner asserts that

> Schlyer discloses identifying areas comprising anatomical changes from an MRI image [0016] and imaging the brain ([0003], [0033]) . . . . [T]his inherently includes identifying evidence of changes in the anatomy, as some sort of "evidence" would have to be found in order to determine the presence of the changes as well as determining evidence of those changes in the brain. Vascular changes are anatomical changes, and Schlyer does not exclude any particular types of changes as not being identifiable using the disclose[d] method/device. Identifying evidence of vascular changes using MRI would, therefore, be obvious based on Schlyer's teachings.

(Ans. 17–18.)

Appellants, however, contend that "none of paragraphs 0008, 0040, 0041, or 0057 [of Schlyer] disclose or discuss any identification of evidence for a brain region with vascular change in an MRI image." (App. Br. 28.) Appellants further contend that "these portions [of Schlyer] cannot be said to 'inherently [include] identifying evidence of changes in the anatomy,' as alleged by the Examiner." (Reply Br. 10.)

Appellants' arguments are persuasive. The Examiner has not sufficiently explained where Schlyer, Mark, or Sibbitt teach or suggest that the anatomical change is a vascular change, nor sufficiently explained the modifications that would be predictably made by the skilled artisan to produce a method with this claimed step. "[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." *In re Kahn,* 441 F.3d 977, 988 (Fed. Cir. 2006).

For the reasons above, the rejection of independent claim 1 is reversed. We also reverse the rejection of claims 4–6, 10, and 19 because of their dependencies from claim 1.

Claims 11 and 18:

Based on the preponderance of the evidence, we agree with the Examiner that claim 11 and 18 would have been obvious over Schlyer, Mark, and Sibbitt. We address Appellants' arguments below.

Claims 11 and 18 are drawn to "[a]n imaging arrangement for detecting a brain region with neurodegenerative change and also a brain

region with vascular change in the brain of a patient." (App. Br. 45 and 47 (Claims App'x).)

Claim 11 requires, among other things, "a control and evaluation system to control the imaging arrangement to[:]" (a) "identify evidence for a brain region with vascular change in the MRI image," (b) "identify a brain region with neurodegenerative change in the PET image," and (c) "superpose, in response to observing a changed brain region in the PET image, the PET image and the segmented MRI image on the display to determine whether the identified brain region with neurodegenerative change is present in gray matter or in white matter." (App. Br. 45–46 (Claims App'x).)

Claim 18 requires, among other things, (a) "means for identifying evidence for a brain region with vascular change in the MRI image," (b) "means for identifying a brain region with neurodegenerative change in the PET image," and (c) "means for superposing, in response to observing a changed brain region in the PET image, the PET image and the segmented MRI image to determine whether the identified brain region with neurodegenerative change is present in gray matter or in white matter." (App. Br. 47–48 (Claims App'x).)

Appellants indicate that "the arguments set forth above with regard to independent claim 1 also apply *mutatis mutandis* to the rejection of independent claim[s] 11 [and 18] under 35 U.S.C. § 103(a) as unpatentable over Schlyer in view of Mark, and further in view of Sibbitt." (*See* App. Br. 32–33).

Appellants' arguments are unpersuasive as to claims 11 and 18.

Schlyer teaches "[a] combined PET/MRI scanner generally includes a magnet for producing a magnetic field suitable for magnetic resonance imaging." (FF 1.) Schlyer also teaches that

> although PET provides advanced functional information with a very high sensitivity, a major problem in PET imaging is the lack of anatomical information. . . . While CT provides excellent contrast for bone structures, magnetic resonance imaging (MRI) yields excellent soft tissue contrast. *Therefore, it would be desirable to combine the diagnostic benefits of a PET scanner with those of an MRI scanner.*

(FF 2 (emphasis added).) Schlyer further teaches

> There are many reasons for combining the functional information from PET with the anatomical (MRI), functional (fMRI) and spectroscopic (MRS) images that can be obtained with MR systems. For example, exploring relationships between structure and function by simultaneous mapping of PET and MR images, the ability to compare different brain mapping techniques such as fMRI and PET, accurate *registration of PET and MR images*, partial volume correction of PET data, temporal correlation of PET and MR spectroscopic images and motion correction of PET studies to permit imaging in conscious animals.

(FF 3 (emphasis added).)

During prosecution, we give claim terms the broadest reasonable interpretation as understood by a person of ordinary skill in the art in light of the specification. *In re Morris*, 127 F.3d at 1054 (Fed. Cir. 1997); *In re Am. Acad. Of Sci. Tech. Ctr.*, 367 F.1359, 1364 (Fed. Cir. 2004) ("Construing claims broadly during prosecution is not unfair to the applicant . . . because the applicant has the opportunity to amend the claims to obtain more precise claim coverage.")

Appellants' Specification does not define "superposing." The Specification discloses, however, that an "MRI image is subdivided by

segmentation into gray matter and white matter - for example into cortex and non-cortex - and the result of the segmentation is transferred to the PET image by *fusion* with it. *In other words, the two images are superposed.*" (*Id.* at ¶ 10 (emphasis added); *see also id.* at ¶ 39.) Schlyer's "accurate registration of PET and MR images" (Schlyer ¶ 16) is reasonably understood as, in some manner, joining and arranging the PET and MR images so the respective image locations are the same. Applying the broadest reasonable interpretation, we thus conclude that the skilled artisan would have predictably used Schlyer's combined PET/MRI scanner to "superpose" the images.

Moreover, as noted above, claims 11 and 18 are apparatus claims that recite "a control and evaluation system to . . .," and "means for . . .," respectively. As such, each of the limitations listed above for items (a), (b), and (c), relates to an intended use of the imaging arrangement. "'Functional' terminology may render a claim quite broad. By its own literal terms a claim employing such language covers any and all embodiments which perform the recited function." *In re Swinehart*, 439 F.2d 210, 213 (CCPA 1971). The imaging arrangement of Schlyer, Mark, and Sibbitt, as modified by the Examiner, could readily (a) "identify evidence for a brain region with vascular change in the MRI image," (b) "identify a brain region with neurodegenerative change in the PET image," and (c) "superpose, in response to observing a changed brain region in the PET image, the PET image and the segmented MRI image on the display to

determine whether the identified brain region with neurodegenerative change is present in gray matter or in white matter." (FF 1–5[9].)

We thus affirm the rejection of claims 11 and 18.

REJECTIONS III–IX

Having reversed the rejection of independent claim 1, we also reverse the rejection of claims 2, 3, 7, 8, 12–17, 20, and 21 because of their dependencies from claim 1.

CONCLUSION OF LAW

We reverse the rejection of claim 21 under 35 U.S.C. § 112, second paragraph, as being indefinite.

We reverse the rejection of claims 1, 4–6, 10, and 19 under 35 U.S.C. § 103(a) over Schlyer, as evidenced by Mark, and Sibbitt.

We affirm the rejection of claims 11 and 18 under 35 U.S.C. § 103(a) over Schlyer, as evidenced by Mark, and Sibbitt.

We reverse the rejection of claims 2 and 13–15 under 35 U.S.C. § 103(a) over Schlyer, as evidenced by Mark, Sibbitt, and Mueller.

We reverse the rejection of claim 3 under 35 U.S.C. § 103(a) over Schlyer, as evidenced by Mark, Sibbitt, and Weese.

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[9] We observe that Schlyer teaches that "[s]ince glucose normally fuels brain activity, the more active a part of the brain is during some experimental task, the more glucose it uses and the higher concentration of glucose in that part of the brain is revealed in the generated PET image." (Schyler ¶ 6.)

We reverse the rejection of claims 7 and 8 under 35 U.S.C. § 103(a) over Schlyer, as evidenced by Mark, Sibbitt, and Salb.

We reverse the rejection of claim 12 under 35 U.S.C. § 103(a) over Schlyer, as evidenced by Mark, Sibbitt, Mueller, and Weese.

We reverse the rejection of claims 16 and 17 under 35 U.S.C. § 103(a) over Schlyer, as evidenced by Mark, Sibbitt, Mueller, and Salb.

We reverse the rejection of claim 20 under 35 U.S.C. § 103(a) over Schlyer, as evidenced by Mark, Sibbitt, and Marks.

We reverse the rejection of claim 21 under 35 U.S.C. § 103(a) over Schlyer, as evidenced by Mark, Sibbitt, Mueller, and Marks.

AFFIRMED-IN-PART